Division 3. Air Resources Board

Chapter 1. Air Resources Board

Subchapter 7.5. Airborne Toxic Control Measures

§ 93108. Ethylene Oxide Airborne Toxic Control Measure--Part 1 - Non-Commercial Sterilizers and Aerators and Commercial Sterilizers and Aerators Using Less Than 2,000 Pounds of Ethylene Oxide per 12 Consecutive Months.

(a) Definitions. For the purposes of this section, the following definitions shall apply:

(1) "Acute care facility" means any facility currently licensed by the California Department of Health Services as a general acute care hospital (as defined in title 22, CCR, section 70005), or any military hospital.

(2) "Aeration" is the process during which residual ethylene oxide dissipates, whether under forced air flow, natural or mechanically assisted convection, or other means, from previously sterilized materials after the sterilizer cycle is complete.

(3) "Aeration-only facility" means a facility which performs aeration on materials which have been sterilized with ethylene oxide at another facility.

(4) "Aerator" means any equipment or space in which materials previously sterilized with ethylene oxide are placed or remain for the purpose of aeration. An aerator is not any equipment or space in which materials that have previously undergone ethylene oxide sterilization and aeration can be handled, stored, and transported in the same manner as similar materials that have not been sterilized with ethylene oxide.

(5) "Aerator exhaust stream" means all ethylene oxide-contaminated air which is emitted from an aerator.

(6) "Back-draft valve exhaust stream" is the air stream which results from collection of ethylene oxide-contaminated air which may be removed from the sterilizer through a back-draft valve or rear chamber exhaust system during unloading of the sterilized materials.

(7) "Commercial sterilizer" means any facility which as its principal business sterilizes products or equipment manufactured elsewhere, or a facility which sterilizes products or equipment it manufactures. A commercial sterilizer is also a non-medical facility that sterilizes items used in conducting its business.

(8) "Control device" means an article, machine, equipment, or contrivance which reduces the amount of ethylene oxide between its inlet and outlet and which is sized, installed, operated, and maintained according to good engineering practices, as determined by the district.

(9) "Control efficiency" is the ethylene oxide (EtO) mass or concentration reduction efficiency of a control device, as measured with ARB Test Method 431 (title 17, CCR, section 94143) according to the source testing requirements herein, and expressed as a percentage calculated across the control device as follows:

$$\frac{\Sigma \text{ EtO in - EtO out}}{\Sigma \text{ EtO in}} \times 100 = \% \text{ Control Efficiency}$$

(10) "District" means the local air pollution control district or air quality management district.

(11) "Ethylene oxide (EtO)" is the substance identified as a toxic air contaminant by the Air Resources Board in 17 CCR section 93000.

(12) "Facility" means any entity or entities which: own or operate a sterilizer or aerator, are owned or operated by the same person or persons, and are located on the same parcel or contiguous parcels of land.

(13) "Facility-wide pounds of ethylene oxide used per year" is the total pounds of ethylene oxide used in all of the sterilizers at the facility during a one-year period.

(14) "Leak-free" refers to that state which exists when the concentration of sterilant gas measured 1 cm. away from any portion of the exhaust system of a sterilizer or aerator, during conditions of maximum sterilant gas mass flow, is less than:

(A) 30 ppm for sterilant gas composed of 12% ethylene oxide/88% chlorofluorocarbon-12 by weight; and

(B) 10 ppm for other compositions of sterilant gas, as determined by ARB Test Method 21 (title 17, CCR, section 94124) using a portable flame ionization detector or a non-dispersive infrared analyzer, calibrated with methane, or an acceptable alternative method or analytical instrument approved by the district. A chlorofluorocarbon-12 specific audible detector using a metal oxide semi-conductor sensor shall be considered an acceptable alternative for exhaust systems carrying a sterilant gas mixture of ethylene oxide and chlorofluorocarbon-12.

(15) "Local medical emergency" means an unexpected occurrence in the area served by the acute care facility resulting in a sudden increase in the amount of medical treatments which require a significant increase in the operation of a sterilizer or aerator.

(16) “Non-commercial sterilizer” means a facility other than a commercial facility at which ethylene oxide is used for sterilizing or fumigation, or at which aeration occurs.

(17) “Sterilant gas” means ethylene oxide or any combination of ethylene oxide and (an)other gas(es) used in a sterilizer.

(18) “Sterilizer” means any equipment in which ethylene oxide is used as a biocide to destroy bacteria, viruses, fungi, and other unwanted organisms on materials. Equipment in which ethylene oxide is used to fumigate foodstuffs is considered a sterilizer.

(19) “Sterilizer cycle” means the process which begins when ethylene oxide is introduced into the sterilizer, includes the initial purge or evacuation after sterilization and subsequent air, steam or other washes, and ends after evacuation of the final wash.

(20) “Sterilizer door hood exhaust stream” is the air stream which results from collection of fugitive ethylene oxide emissions, by means of an existing hood over the sterilizer door, during the time that the sterilizer door is open after the sterilizer cycle has been completed.

(21) “Sterilizer exhaust stream” is all ethylene oxide-contaminated air which is intentionally removed from the sterilizer during the sterilizer cycle.

(22) “Sterilizer exhaust vacuum pump” means a device used to evacuate the sterilant gas during the sterilizer cycle, including any associated heat exchanger. A sterilizer exhaust vacuum pump is not a device used solely to evacuate a sterilizer prior to the introduction of ethylene oxide.

(b) Applicability. Effective January 28, 1999, any person who owns or operates any non-commercial sterilizer or aerator or any person who owns or operates a commercial sterilizer or an aerator that uses less than 2,000 pounds of EtO per consecutive 12-month period after December 6, 1996, must comply with Part I of this regulation, section 93108.

(c) Notification. Any person subject to this regulation must provide the district with the following information, in writing, within 30 days of the date of district adoption:

(1) the name(s) of the owner and operator of the facility;

(2) the location of the facility;

(3) the number of sterilizers and aerators at the facility; and

(4) an estimate of the total pounds of ethylene oxide and sterilant gas used by the facility, in all sterilizers, during the previous calendar year, as determined by a method approved by the district.

A district may exempt a source from this requirement if the district maintains current equivalent information on the source.

(d) Reporting. Any person who owns or operates a sterilizer shall furnish a written report to the district annually on the date specified by the district, or, at the district's discretion, shall maintain such a report and make it available to the district upon request. Commercial sterilizers shall maintain copies of these reports on site for 5 years. This report shall include one of the following, as determined by the district:

(1) the number of sterilizer cycles and the pounds of ethylene oxide used per cycle for each sterilizer during the reporting period, as determined by a method approved by the district; or

(2) the total pounds of sterilant gas and the total pounds of ethylene oxide purchased, used, and returned in the previous calendar year, as determined by a method approved by the district.

(e) Requirements. No person shall operate a sterilizer or aerator unless all of the following requirements are satisfied:

(1) the exhaust systems and EtO supply system including, but not limited to, any piping, ducting, fittings, valves, or flanges, through which ethylene oxide-contaminated air is conveyed between the sterilizer, aerator and the control device shall be leak-free;

(2) all of the control requirements shown in Table I below for the applicable control category are met;

(3) the average concentration of ethylene oxide shall not exceed:

(A) 30 mg/ml in any liquid discharge associated with the sterilization cycle; and

(B) 10 mg/ml in any liquid discharge associated with the aeration cycle for those facilities where Table I requires aeration control;

Table I
Control and Compliance Requirements

Control Category		*Requirements*	
	(a)	*(b)*	*(c)*
Facility-wide Pounds of Ethylene Oxide Used Annually	*Exhaust Streams to be Controlled*	*Exhaust Streams to be Tested*	*Control Efficiency (%)*
Less than or equal to 25	None	None	None
More than 25 and less than or equal to 600	Sterilizer	Sterilizer	99.0
More than 600 and less than or equal to 5,000	Sterilizer Aerator Sterilizer/Aerator Back-draft Valve	Sterilizer Aerator Sterilizer/Aerator	99.9 95.0 99.7 N/A*
More than 5,000	Sterilizer Aerator Sterilizer Door Hood & Back-draft Valve	Sterilizer Aerator	99.9 99.0 N/A* N/A*
Aeration-only Facilities	Aerator	Aerator	95.0

* Not Applicable

(4) for facilities using more than 600 pounds of ethylene oxide per year, the back-draft valve is ducted to the control device used to control the sterilizer exhaust stream or the aerator exhaust stream; and

(5) for facilities using more than 5,000 pounds of ethylene oxide per year, the sterilizer door hood exhaust stream is ducted to the control device used to control the aerator exhaust stream.

(f) Exemptions:

(1) The requirements set forth in subsection (e) above do not apply to any facility which treats materials in a sterilizer and which uses a total of 25 pounds or less of ethylene oxide per calendar year.

(2) The district hearing board may grant an emergency variance from items (a) and (c) in Table I of Part 1 subsection (e), Requirements, to a person who owns or operates an acute care facility if response to a local medical emergency requires increased operation of a sterilizer or aerator such that the requirements cannot be met.

The demonstrated need for such increased operation shall constitute “good cause” pursuant to Health and Safety Code section 42359.5. The emergency variance shall be granted in accordance with this section and any applicable district rule regarding the issuance of emergency variances for such occurrences, including the requirement that the emergency variance shall not remain in effect longer than 30 days; however, the emergency variance shall be granted only for the period of time during which increased operation of a sterilizer or aerator is necessary to respond to the local medical emergency.

(g) Compliance. For the purpose of determining compliance with the control efficiency requirement set forth in column (c) of Table I, subsection (e), if a reduction in the amount of ethylene oxide across the control device is demonstrated, but the control efficiency cannot be affirmatively demonstrated because the concentration of ethylene oxide measured in the outlet of the control device is below 0.2 parts per million ethylene oxide, the facility shall be considered to be in compliance with this requirement.

(h) Source Testing. Source testing shall be conducted according to ARB Test Method 431 (title 17, CCR, section 94143) and the method evaluations cited therein or an acceptable source test method approved by the district

with the concurrence of the Executive Officer of the Air Resources Board. Specific requirements for application are given below.

(1) All ethylene oxide emission points shall be sampled during the entire testing period.

(2) If the efficiency is being determined by inlet and outlet sampling, the inlet and outlet of the control device shall be sampled simultaneously during testing.

(3) The efficiency of each control device shall be determined under conditions of maximum ethylene oxide mass flow to the device, under normal operating conditions. To measure the control efficiency of the control device on the sterilizer exhaust stream, sampling shall be done during the entire duration of the first sterilizer evacuation after ethylene oxide has been introduced. To measure the control efficiency of the control device on an aerator exhaust stream with a constant air flow, sampling shall be done during a period of at least 60 minutes, starting 15 minutes after aeration begins. To measure the control efficiency of the control device on an aerator exhaust stream with a non-constant air flow, sampling shall be done during the entire duration of the first aerator evacuation after aeration begins.

(4) There shall be no dilution of the air stream between the inlet and outlet test points during testing.

NOTE: Authority cited: Sections 39600, 39601 and 39666, Health and Safety Code. Reference: Sections 39650, 39656, 39658, 39659, 39665, 39666 and 42359.5, Health and Safety Code; and 40 CFR Part 63 Subpart O.

REFERENCE